



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/864,891

05/24/2001

Kok-Hwee Ng

F-5735 (1417P P 599)

2261

7590 03/21/2007
Bradford R. L. Price Esq.
Senior Counsel
Baxter International Inc.
Route 120 and Wilson Road, RLP-30
Round Lake, IL 60073

EXAMINER

TOMASZEWSKI, MICHAEL

ART UNIT

PAPER NUMBER

3626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
--	-----------	---------------

3 MONTHS

03/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 09/864,891	Applicant(s) NG ET AL.	
	Examiner Mike Tomaszewski	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice To Applicant

1. This communication is in response to the amendment filed on 1/5/07. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/5/07 has been entered.

Claims 1-7 were cancelled. Claims 8, 31 and 43 are currently amended. Claims 8-54 are pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3626

3. Claims 8-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fletcher-Haynes et al. (US 2001/0034614; hereinafter Fletcher), in view of Withers (5,752,234; hereinafter Withers).

(A) As per currently amended claim 8, Fletcher discloses a system for managing inventory of blood component collection soft goods and for preventing the use of quarantined soft goods, the system comprising:

- (1) a blood component collection instrument for collecting a blood component from a blood component donor in a blood component soft good (Fletcher: par. [0056] and [0125]; Examiner notes, in particular, that Fletcher teaches that the blood/blood components are collected into "bags" via "tubing sets" (i.e., "blood component soft goods" or "the container or kit which holds the collected blood component," as defined by Applicant on pg. 14 of Applicant's response filed 6/30/2006));
- (2) a system computer being operably connected to the blood component collection instrument (Fletcher: par. [0057]), the system computer running a blood component collection application for at least a portion of a blood component collection process (Fletcher: par. [0057]), wherein the system computer is in data communication with a system database having a blood component collection soft good inventory (Fletcher: par. [0056], [0063], and [0195]); and,

Art Unit: 3626

- (3) an interface being operably connected to the system computer (Fletcher: par. [0057]).

Examiner notes that Fletcher teaches the use of a multitude of graphical user interfaces (GUIs) having numerous fields for indicating a variety of things including blood component inventory levels, machine identification numbers, blood collection bag identification numbers, blood component collection volumes, tubing set identification numbers, etc. (Fletcher: Figs. 2A-6M). As such, Examiner considers GUIs having various inventory indication fields to be notoriously well known.

Fletcher, however fails to *expressly* disclose a system for managing inventory of blood component collection soft goods and for preventing the use of quarantined soft goods, the system comprising:

- (4) a system computer, wherein the system computer is in data communication with a system database having a blood component collection soft good inventory and quarantine information relative thereto, and said system computer processes said inventory and quarantined information; and
- (5) the interface having a quarantine field for indicating that at least a portion of the blood component collection soft good inventory is quarantined based on the processing of the inventory and quarantined information.

Art Unit: 3626

Nevertheless, these features are old and well known in the art, as evidenced by Withers. In particular, Withers discloses a system for managing inventory of blood component collection soft goods and for preventing the use of quarantined soft goods, the system comprising:

- (4) a system computer, wherein the system computer is in data communication with a system database having a blood component collection soft good inventory and quarantine information relative thereto, and said system computer processes said inventory and quarantined information (Withers: abstract); and
- (5) the interface having a quarantine field for indicating that at least a portion of the blood component collection soft good inventory is quarantined based on the processing of the inventory and quarantined information (Withers: abstract).

One of ordinary skill would have found it obvious at the time of the invention to combine the teachings of Withers with the teachings of Fletcher with the motivation of providing a comprehensive system for tracking quarantined medical soft goods (Withers: col. 1, line 65-col. 2, line 2).

(B) As per original claim 9, Fletcher discloses the system of claim 8, wherein the interface communicates to the system database an identification of the soft goods

Art Unit: 3626

(Fletcher: par. [0022], [0083], [0125], and [0162]) (Examiner notes also that Fletcher teaches the use of various GUI comment fields whereby a user of the system could indicate that a particular soft good is unsuitable (i.e., quarantined)).

Fletcher, however, fails to *expressly* disclose the system of claim 8, wherein the interface communicates to the system database an identification of the [*quarantined*] soft goods.

Nevertheless, this feature, as aforementioned, is old and well known, as evidenced by Wither. In particular, Wither discloses the system of claim 8, wherein the interface communicates to the system database an identification of the quarantined soft goods (Wither: abstract).

One of ordinary skill would have found it obvious at the time of the invention to combine the teachings of Withers with the teachings of Fletcher with the motivation of providing a comprehensive system for tracking quarantined medical soft goods (Withers: col. 1, line 65-col. 2, line 2).

(C) As per original claim 10, Fletcher discloses the system claim 8, wherein the blood component collection soft good is selected from a group consisting of blood component collection kit (Fletcher: par. [0022], [0071], [0192], and [0315]) (Examiner considers a barcode, needle, receptacle bag, tubing set, and blood containers, among other soft goods to read on "blood component collection kit.").

Art Unit: 3626

Examiner has noted insofar as claim 10 recites "selected from a group consisting of blood component collection kit, a blood component collection solution, and a blood component collection transfer pack," a blood component collection kit has been recited.

(D) As per original claim 11, Fletcher discloses the system of claim 8, wherein the interface further comprises a reader being operably connected to the system computer for receiving an operator identifier and transmitting the operator identifier to the system computer, and for receiving separate input of a blood component soft good identifier and transmitting the blood component soft good identifier to the system database (Fletcher: par. [0022], [0059], [0071], [0079], [0083], and [0125]).

In short, Fletcher teaches a system replete with a myriad of identifiers (e.g., operator identifiers, instrument/device/identifiers, donor identifiers, soft good identifiers, inventory identifiers, etc.) being received and transmitted by the system computer in conjunction with an array of peripheral devices (e.g., barcode readers, scanners, cameras, etc.) (Fletcher: par. [0022], [0059], [0071], [0079], [0083], and [0125]).

(E) As per original claim 12, Fletcher discloses the system of claim 11, wherein the operator identifier and a blood component collection soft good identifier are received from a location proximate the blood component collection instrument (Fletcher: par. [0022], [0058], [0059], [0079], [0083], and [0125]).

Art Unit: 3626

(F) As per original claim 13, Fletcher discloses the system claim 8, wherein the system database is integral with the system computer (Fletcher: par. [0057] and [0058]).

In fact, Fletcher teaches multiple system configurations including, but not limited to, one where the system database can be included therein (i.e., integral within the computer), one where the system database is positioned in close proximity with the system computer (i.e., integral to the computer system), and one where the system database is located remotely (i.e., integral to the computer system network) (Fletcher: par. [0057] and [0058]).

(G) As per original claim 14, Fletcher discloses the system of claim 8, further comprising a blood component collection donor identifier corresponding to a blood component donor, wherein the blood component collection donor identifier is transmittable to the system computer for storing the blood component collection donor identifier in the memory and for associating the blood component collection donor identifier with at least one of the blood component collection soft good identifier and the blood collection instrument identifier (Fletcher: par. [0022], [0068], [0124], [0125], [0142] and [0159]; Fig. 2A-6M).

(H) As per original claim 15, Fletcher discloses the system of claim 8, wherein the blood component collection instrument further comprises a blood component collection instrument identifier (Fletcher: par. [0159]; Fig. 4A).

(I) As per original claim 16, Fletcher discloses the system claim 8, wherein the interface utilizes radio frequency to transmit to the system computer (Fletcher: par. [0059]).

In fact, Fletcher teaches an open computer system architecture that may leverage a broad assortment of interface transmission means including cable, satellite, and energy wave communication, among other transmission means (Fletcher: par. [0059]).

(J) As per original claim 17, Fletcher discloses the system of claim 8, further comprising:

- (a) a system communication conduit for operably connecting the system computer to the blood component collection instrument (Fletcher: par. [0012]); and,
- (b) a system communication protocol for facilitating communication on the communication conduit between the system computer and the blood component collection instrument (Fletcher: par. [0030]).

(K) As per original claim 18, Fletcher discloses the system of claim 17, wherein the system communication protocol is Ethernet (Fletcher: par. [0030]).

Art Unit: 3626

(L) As per original claim 19, Fletcher discloses the system of claim 17, wherein the system communication protocol is TCP/IP (Fletcher: par. [0030] and [0194]).

(M) As per original claim 20, Fletcher discloses the system of claim 17, further comprising:

- (a) a network server being operably connected to the system computer via a network communication conduit (Fletcher: par. [0012] and [0065]); and
- (b) a web interface being operably connected to the system computer for facilitating access to the blood component collection process, wherein the interface receives data from the system computer (Fletcher: par. [0033] and [0194]).

(N) As per original claim 21, Fletcher discloses the system of claim 20, further comprising a web server being operably connected to the system computer and operably responsive to a web browser wherein the information stored in the system computer can be accessed (Fletcher: par. [0033] and [0194]).

(O) As per original claim 22, Fletcher discloses the system of claim 20, wherein the interface comprises a reader having at least one of a touch pad (Fletcher: par. [0057]).

Examiner has noted insofar as claim 22 recites "at least one of a touch pad, a keypad, an optical scanner, and a magnetic scanner" a touch pad has been recited.

(P) As per original claim 23, Fletcher discloses the system of claim 8, wherein the system database further comprises separate inventory data for each of a plurality of different types of soft goods (Fletcher: par. [0011] and [0166]; Figs. 2A-6M).

Examiner notes that Fletcher specifically teaches capturing, tracking, editing, printing, manipulating, measuring, modifying, calculating, transmitting, and receiving various soft goods (e.g., various blood component solutions, such as plasma, red blood cells, etc.; blood collection kits including needles, blood collection bags, etc.) inventory data pertinent to the blood collection process (Fletcher: par. [0011] and [0166]; Figs. 2A-6M).

(Q) As per original claim 24, Fletcher discloses the system of claim 23, wherein the plurality of different types of soft goods is a blood component collection kit (Fletcher: par. [0022], [0071], [0192], and [0315]) (Examiner considers a barcode, needle, receptacle bag, tubing set, and blood containers, among other soft goods to read on "blood component collection kit.").

Examiner has noted insofar as claim 24 recites "selected from group consisting of a blood component collection kit, a blood component collection solution, and a blood component collection transfer pack" a blood component collection kit has been recited.

(R) As per original claim 25, Fletcher discloses the system of claim 8, wherein the blood component soft good inventory data is modified in response to the receipt of the

Art Unit: 3626

blood component soft good identifier transmitted from the interface (Fletcher: par. [0022], [0084], [0125] and [0166]; Figs. 2A-6M).

(S) As per original claim 26, Fletcher discloses the system of claim 25, wherein the system computer generates a notification when the blood component soft good inventory data is modified to a value which is lower than a predetermined value (Fletcher: par. [0314]) (Examiner considers blood component collection solutions (e.g., plasma solutions, red blood cell solutions, etc.) to read on “blood component soft good.”

(T) As per original claim 27, Fletcher discloses the of claim 26, wherein the notification comprises providing a reorder option corresponding to the blood component soft good associated with the blood component soft good identifier (Fletcher: par. [0195]).

(U) As per original claim 28, Fletcher discloses the system of claim 27, wherein the notification is transmitted to a remote access service for restocking blood component soft good inventory (Fletcher: par. [0195] and [0314]).

(V) As per original claim 29, Fletcher discloses the system of claim 8, further comprising a blood component collection kit having a plurality of blood component collection soft goods (Fletcher: par. [0022], [0056], [0063], [0071], [0192], [0195], [0395]).

Art Unit: 3626

(W) As per original claim 30, Fletcher discloses the system of claim 29, wherein the blood component collection kit comprises a blood component container, a hypodermic needle, a blood component sample container, and a label (Fletcher: par. [0022], [0071], [0192], and [0315]).

Examiner considers a barcode (i.e., label), needle, receptacle bag (i.e., blood component container, blood component sample container), tubing set, and blood containers (i.e., sample container), among other soft goods to read on "blood component collection kit."

(X) Currently amended claim 31 differs from system claim 8 by reciting "[a] computer readable medium having computer program code stored thereon..." within its preamble. As per these elements, Fletcher's system and method for managing inventory of blood component collection soft goods includes computers, data storage devices, communication devices, server systems, network systems and software applications running in conjunction with various hardware devices (Fletcher: par. [0020], [0031], [0032] and [0057]). As such, it is readily apparent that Fletcher's system and method for managing the inventory of blood collection soft goods is controlled by a computer program stored upon a computer-readable medium.

The remainder of claim 31 substantially repeats the same limitations of claim 8 and is therefore, rejected for the same reasons given for claim 8 above and incorporated herein.

Art Unit: 3626

(Y) Original claims 32-42 substantially repeat the same limitations of claims 9-12, 14-15 and 25-28, and are therefore, rejected for the same reasons given for those claims.

(Z) Currently amended claim 43 differs from system claim 8 by excluding hardware and software elements, namely, "a blood component collection instrument," "a system computer being operably connected to the blood collection instrument," "the system computer running a blood component collection application," "a system database having a blood component collection soft good inventory," and "an interface being operably connected to the system computer, the interface having a quarantine field." The method merely repeats the underlying process steps of system claim 8 and thus, merely repeats the same limitations of claims 8 and is therefore, rejected for the same reasons given for claim 8 above and incorporated herein.

(AA) Original claims 44-54 substantially repeat the same limitations of claims 9-12, 14-15 and 25-28, and are therefore rejected for the same reasons given for those claims.

Response to Arguments

4. Applicant's arguments filed 1/5/07 have been fully considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MT

~~MA~~

Robert Morgan
Robert Morgan
Patent Examiner
Art Unit 3626